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AMENDMENT

IN THE CLAIMS

1. (currently amended) An orally-administrable formulation for the controlled release of an isoflavone-enriched fraction or mixture of such fractions, said formulation comprising microcapsules containing at least one granulated plant fraction enriched in isoflavones and at least one carrier, diluent or excipient therefor, said formulation being formulated so as to slowly release the isoflavones contained therein by virtue of said microcapsules being formed with a coating comprising a blend of at least two polymers, at least one of said at least two polymers being more hydrophilic than the other of said at least two polymers, the ratio of the less hydrophilic polymer to said more hydrophilic polymer being from about 90:10 to 50:50, said coating being applied to said granulated isoflavone-enriched fraction at a level of about 5 to about 45% by weight of said granulated isoflavone-enriched fraction component.

2. (currently amended) An orally-administrable formulation for the stable storage of an isoflavone-enriched fraction or mixture of such fractions, said formulation comprising microcapsules containing at least one granulated plant fraction enriched in isoflavones and at least one carrier, diluent or excipient therefor, said formulation being formulated so as to substantially maintain the activity of the isoflavones contained therein for at least six months under storage conditions of standard temperature and pressure by virtue of said microcapsules being formed with a coating comprising a blend of at least two polymers, at least one of said at least two polymers being more hydrophilic than the other of said at least two polymers, the ratio of the less hydrophilic polymer to said more hydrophilic polymer being from about 90:10 to 50:50, said coating being applied to said granulated isoflavone-enriched fraction at a level of about 5 to about 45% by weight of the granulated isoflavone-enriched fraction component.

3. (previously presented) An orally-administrable formulation for the controlled release of a granulated isoflavone-enriched fraction or mixture of such fractions according to claim 1, comprising at least one granulated isoflavone-enriched fraction and at least one carrier, diluent or excipient therefor, characterized in that the total in vitro dissolution time of said formulation required for release of 75% of the active ingredients available from said formulation is between about 4 and about 18 hours, as determined by the U.S.P. XXIII paddle method at a paddle speed of 75 rpm, using simulated intestinal fluid without the digestive enzymes normally found in intestinal fluid, at pH 6.8, and a temperature of 37°C.

4. (previously presented) A formulation according to Claim 3 characterized in that the total amount of granulated isoflavone-enriched fractions contained therein is from about 1 to about 95 wt.%.

5. (previously presented) A formulation according to Claim 3, wherein said formulation is in a form selected from the group consisting of: (i) a matrix tablet, (ii) a multicomponent formulation, (iii) a microcapsule of generally spherical shape, (iv) a microcapsule of generally non-spherical shape, (v) a capsule containing microcapsules, and (vi) a tablet containing microcapsules.

6. (previously presented) A formulation according to Claim 3 comprising at least one granulated isoflavone-enriched fraction mixed or coated with an excipient or mixture of excipients selected from the group consisting of synthetic polyvinyl-type polymers, synthetic polyethylene-type polymers, cellulose-type polymers, synthetic polyacrylate-type polymers, fats, waxes, sugars and sugar alcohols.

7. (previously presented) A formulation according to Claim 3 in the form of a tablet comprising: at least one granulated isoflavone-enriched fraction embedded in a mixture of polyvinyl chloride and polyvinyl acetate; and magnesium stearate as a lubricant.

8. (previously presented) A formulation according to Claim 3 in the form of a tablet comprising: at least one granulated isoflavone-enriched fraction embedded in a mixture of polyvinyl chloride and ethyl cellulose; magnesium stearate as lubricant; and a material selected from hydroxypropyl methyl cellulose, sodium carboxymethyl cellulose and paraffin.

9. (previously presented) A formulation according to Claim 3 in the form of a hard gelatin two-piece capsule filled with microcapsules containing at least one granulated isoflavone-enriched fraction.

10. (previously presented) A formulation according to Claim 3 in the form of a tablet comprising microcapsules.

11. (currently amended) A process for the preparation of an orally-administrable formulation for the controlled release of granulated isoflavone-enriched fraction or mixture of such fractions, said ~~preparation~~formulation comprising at least one granulated isoflavone-enriched fraction ~~and at least one carrier, diluent or excipient therefor~~, said process comprising the steps of:

providing at least one granulated isoflavone-enriched fraction,

forming microcapsules by coating granules of said at least one granulated isoflavone enriched fraction with a coating comprising a blend of at least two polymers, at least one of said at least two polymers being more hydrophilic than the other of said at least two

polymers, the ratio of the less hydrophilic polymer to said more hydrophilic polymer being from about 90:10 to 50:50, said coating being applied to said isoflavone-enriched fraction at a level of about 5 to about 45% by weight of the isoflavone-enriched fraction component; and

incorporating said microcapsules~~at least one granulated isoflavone enriched fraction~~ into said ~~at least one carrier, diluent or excipient therefor~~formulation,

wherein said formulation is characterized in that the total in vitro dissolution of said formulation required for release of 75% of the active ingredients from said formulation based upon the total amount of active ingredients present in said formulation is between about 4 and about 18 hours, as determined by the USP XXIII paddle method at a paddle speed of 75 rpm, using simulated intestinal fluid without the digestive enzymes normally found in intestinal fluid, at pH 6.8 and a temperature of 37°C.

12. (currently amended) The process according to Claim 11 characterized in that said at least one granulated isoflavone-enriched fraction is (i) ~~mixed or~~coated with ~~an excipient or mixture of excipients~~a blend of at least two polymers selected from the group consisting of synthetic polyvinyl-type polymers, synthetic polyethylene-type polymers, cellulose-type polymers, synthetic polyacrylate-type polymers, fats, waxes, sugars and sugar alcohols, and (ii) then compressed into tablets. compressed into tablets.

13. (currently amended) The process according to Claim ~~12~~11 characterized in that said~~at least one granulated isoflavone enriched fraction is (i) mixed or coated with an excipient or mixture of excipients selected from the group consisting of synthetic polyvinyl type polymers, synthetic polyethylene type polymers, cellulose type polymers, synthetic polyacrylate type polymers, fats, waxes and sugars, (ii) then processed into a form selected~~

~~from the group of microcapsules and pellets, and (iii) said~~ microcapsules ~~or pellets~~ are filled into hard gelatin capsules.

14. (currently amended) The process according to Claim ~~12~~ 11 characterized in that said ~~at least one granulated isoflavone enriched fraction is (i) mixed or coated with an excipient or mixture of excipients selected from the group consisting of synthetic polyvinyl type polymers, synthetic polyethylene type polymers, cellulose type polymers, synthetic polyacrylate type polymers, fats, waxes and sugars, (ii) then processed into a form selected from the group of microcapsules and pellets, and (iii) said~~ microcapsules ~~or pellets~~ are compressed into tablets.

15. (currently amended) An orally-administrable formulation for the controlled release of a granulated isoflavone-enriched fraction or mixture of such fractions comprising particles of at least one granulated isoflavone-enriched fraction coated with a film comprising a mixture of at least one water soluble polymer and at least one water insoluble polymer, said at least one water soluble polymer and at least one water insoluble polymer being present in a ratio of between about 10:90 and 50:50 and at a level of about 5 to 45% by weight of the granulated isoflavone enriched fraction, that produces a substantially zero order linear release pattern of at least one active ingredient.

16. (previously presented) An orally-administrable formulation according to Claim 15, wherein said particles comprise particles which are non-spherically shaped.

17. (previously presented) An orally-administrable formulation according to Claim 15, wherein said particles comprise particles which are spherically shaped.

18. (previously presented) An orally-administrable formulation according to claim 15, wherein said at least one active ingredient is Deidzein.

19. (previously presented) An orally-administrable formulation according to claim 15, wherein said at least one active ingredient is Genisein.

20. (previously presented) An orally-administrable formulation according to claim 15, wherein said at least one active ingredient is an Glycitain.

21. (currently amended) An orally-administrable formulation for the controlled release of a granulated isoflavone-enriched fraction or mixture of such fractions, comprising particles of at least one granulated isoflavone-enriched fraction coated with an enteric coating comprising a polymer film comprising a ~~polymer~~blend of at least two polymers which is insoluble at a pH below about 5.5, at least one of said at least two polymers being more hydrophilic than the other of said at least two polymers, the ratio of the less hydrophilic polymer to said more hydrophilic polymer being from about 90:10 to 50:50, said coating being applied to said granulated isoflavone-enriched fraction at a level of about 5 to about 45% by weight of the isoflavone-enriched fraction component.

22. (previously presented) An orally-administrable formulation according to Claim 21, wherein said particles comprise particles which are non-spherically shaped.

23. (previously presented) An orally-administrable formulation according to Claim 21, wherein said particles comprise particles which are spherically shaped.

24. (previously presented) A formulation according to Claim 21, wherein said polymer is soluble at a pH of about 5.5 or higher.

25. (previously presented) A formulation according to Claim 21, wherein said polymer is insoluble at a pH below about 5.0.

26. (previously presented) A formulation according to Claim 21, wherein said polymer is hydroxypropylmethyl cellulose phthalate.

27. (previously presented) A formulation according to Claim 21, wherein said polymer is cellulose acetate phthalate.

28. (previously presented) A formulation according to Claim 15 wherein said water insoluble polymer is ethyl cellulose.

29. (previously presented) A formulation according to Claim 15 wherein said water soluble polymer is hydroxypropylmethyl cellulose (HPMC).

30. (previously presented) A formulation according to Claim 15 wherein said water insoluble polymer is ethyl cellulose and said water soluble polymer is hydroxypropylmethyl cellulose (HPMC), and wherein the HPMC/ethyl cellulose ratio is substantially from about 0.05 to about 0.40.

31. (previously presented) A formulation according to Claim 15 wherein the total content of granulated isoflavone-enriched fractions is between about 1 to 95 wt. %.

32. (currently amended) A process for producing an orally-administrable formulation for the controlled release of a granulated isoflavone-enriched fraction or mixture of such fractions, comprising coating particles of at least one granulated isoflavone-enriched fraction with an inner, mixed polymer film comprising ethyl cellulose and hydroxypropylmethyl cellulose (HPMC), wherein the HPMC/ethyl cellulose ~~ration~~ratio is substantially from about 0 to about 0.40 by weight, and then coating said particles coated with said inner polymer film with an outer polymer film comprising hydroxypropylmethyl cellulose phthalate, wherein the weight ratio of the outer to inner polymer layers is between 0.2 to 3.0, and wherein said coating is applied at a level of about 5 to 45% by weight of said granulated isoflavone enriched fraction.